REMARKS/ARGUMENTS

Claims 1-21 are pending.

No new matter has been added.

Applicants respectfully traverse the obviousness rejection of Claims 1-21 as being unpatentable over Nelson in view of Fritsch, because neither of the references describes or suggests the limitation, found for example in Claim 1, that the composition comprise a salt [made up] of L-ascorbic acid and a pharmaceutically acceptable organic base, or the limitation of for example, Claim 2, wherein the pharmaceutically acceptable organic base is selected from tromethamine, N-methylglucosamine, lysine, arginine and ornithine.

Nelson describes metal salts of racemic aspartic acid. That the salts of Nelson are metal salts is shown at column 3, line 15, describing sodium and potassium, and column 3, lines 7-8, which describes sodium ascorbate.

Nelson further describes, at column 4, line 37, adding tromethamine to the composition containing a metal salt of racemic aspartic acid.

Thus, the composition of <u>Nelson</u> contains a metal salt of racemic ascorbic acid and, for example, tromethanine, shown below:

$$\left[\begin{array}{c} Ascorbic \\ Acid \end{array} \right] \begin{array}{c} \ominus \\ O \\ Na \end{array} \begin{array}{c} + \\ \end{array} \left[\begin{array}{c} Tromethamine \\ - \\ \end{array} \right] \begin{array}{c} \bullet \\ NH_2 \\ - \end{array}$$

As can be seen in the drawing, the ascorbic acid salt is an ion pair, with an oxygen on ascorbic acid being negatively charged, and the counter ion, sodium, being positively charged. The amino group of tromethamine is neutral, it has no charge, although it does have a free pair of electrons on the amine nitrogen.

Attempting to form an Ascorbic Acid – Tromethamine salt form this mixture, as the Office is intending to do, is contrary to the laws of chemistry, and incorrect. Thus, removing

the metal (sodium) from the metal salt of ascorbic acid, and trying to replace the metal with charge neutral Tromethamine would give the situation shown below:

$$\begin{bmatrix} & \text{Ascorbic} \\ & \text{Acid} & \end{bmatrix} \longrightarrow \begin{bmatrix} \ominus & \mathbf{0} \\ & \mathbf{0} \\ & \mathbf{H_2N} & \end{bmatrix}$$
 Tromethamine

In this situation, the amino group of Tromethamine is neutral, and thus cannot be the cationic component of the salt, and thus cannot form a salt. Further, the electron density of the free electron pair on the nitrogen of Tromethamine would actually repel the anionic oxygen of racemic ascorbic acid.

Thus, <u>Nelson</u> describes a composition containing a metal salt of racemic ascorbic acid together with Tromethamine, whereas the present claims describe a salt made up of a protonated cationic organic base and an anionic L-aspartate ion (see below):

$$\begin{bmatrix} & \text{Ascorbic} \\ & \text{Acid} \end{bmatrix} \xrightarrow{\Theta} \begin{bmatrix} & & & \\ & & & \\ & & & \end{bmatrix} \text{Tromethamine} \end{bmatrix}$$

Accordingly, <u>Nelson</u> does not describe or suggest a key limitation of the pending claims, and the disclosure of <u>Fritsch</u>, in its addition of ibuprofen, does not remedy the deficiency of <u>Nelson</u>.

Withdrawal of the obviousness rejection is respectfully requested.

Further, Applicants respectfully submit that the Office has improperly rejected the pending method claims of the application, and has given no reasons for the rejection of these claims. Applicants note that method Claim 11 is an independent claim, and that a limitation of Claim 11 requires topically administering a composition to the eye in a patient in need thereof. Fritsch is drawn to an orally administered effervescent ibuprofen containing

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preparation. <u>Nelson</u> is drawn to a contact lens cleaning solution. There is no teaching or suggestion to administer either of these compositions topically into the eye of a patient in need thereof.

Applicants submit the present application is now in condition for allowance. Early notification to this effect is earnestly solicited.

Respectfully submitted,

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